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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E-2463/04		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/052914		International filing date (day/month/year) 10.11.2004		Priority date (day/month/year) 11.11.2003
International Patent Classification (IPC) or national classification and IPC A61N2/02				
Applicant IGEA S.R.L. et Al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 22.03.2005		Date of completion of this report 22.02.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Rakotondrajaona, C Telephone No. +31 70 340-2881 		

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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/052914

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-13 as originally filed

Claims, Numbers

1-15 filed with telefax on 22.03.2005

Drawings, Sheets

1/4-4/4 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/052914

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12-15

because:

☒ the said international application, or the said claims Nos. 12-15 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 12-15

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2004/052914

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-11
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1-11
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2004/052914

Re Item III.

Method claims 12-15 define a method for treatment of the human or animal body by therapy or surgery practised on the human or animal body. Therefore, no preliminary international examination is required for the subject-matter of these method claims (see Article 34 (4) (a) (I) PCT and Rule 67.1 (iv) PCT).

Re Item V.

1. The following documents are referred to in this communication:

D1 : US 2003/093028 A1 (SPIEGEL MICHAEL) 15 May 2003 (2003-05-15)
D2 : EP-A-1 138 348 (MEDISCAN GMBH) 4 October 2001 (2001-10-04)
D3 : US-A-4 587 957 (JOHN C. CASTEL) 13 May 1986 (1986-05-13)

2. INDEPENDENT CLAIM 1

- 2.1 The feature "for Anatomic Biophysical Chondroprotection" is not a feature of the device but merely defines the intended purpose of the device. Therefore, it does not clearly limit the subject matter of claim 1.
- 2.2 The feature "directed on a part of the human body (26) including cartilaginous tissue (27)" is a method step and not a feature of the device. Therefore, it does not clearly limit the subject matter of claim 1.
- 2.3 Document D1 discloses (the references in parentheses applying to this document) the following features of claim 1:

an electromagnetic field stimulator (page 4, col. 2, paragraph 63), in which means of current generation (19, 20) are suitable for powering at least one solenoid (17, 16) to generate an electromagnetic field (18), characterised in that the said means for current generation supplies said solenoid (17, 16) with current $I(t)$ having a waveform (23) that includes the repetition of a linear ramp with a certain slope (see figure 6, ref. 23, in combination with paragraph 75).

Remarks

1- The electromagnetic field generated by solenoid (17, 16) is itself generated by a current flowing through this solenoid. It appears that in "normal conditions", the electromagnetic field generated by a solenoid is proportional to the current flowing through the solenoid. Therefore, since the generated electromagnetic field is

increasing linearly, the current generating this electromagnetic field is also increasing linearly. Paragraph 75, clearly states that a "stepwise increasing current" is applied to the electromagnets.

2- Figure 7 displays a continuous, linearly increasing magnetic field, and the repetition of a ramp with a certain slope. There is no difference between the curve of figure 7 and claim 1.

3- The "linear ramp" of claim is obtained by using a table memory (7, fig. 1) wherein current profiles are stored in digital forms; the use of a Digital to Analog Converter (19) is necessary in that case D/A, another Analog to Digital Converter (30) is used in the feedback loop. It is well known in digital electronics that memories store discrete values, conversely to analog values. Therefore, the current generated by table memory (7) is also a stepwise increasing current, the only difference could be the magnitude of the steps.

The feature "said current ($I(t)$) causing the generation of an electromagnetic field that induces on a control probe irradiated by said electromagnetic field, a voltage of markedly constant amplitude during the ramp-like linear growth period of said current." lacks clarity (see Item VIII below).

However, as far as it can be understood, this feature merely appears to indicate that the current increases linearly as a function of the time. This is also the case with the device of D1 because the indicated magnetic field (see figure 7) clearly increases linearly as a function of the time and said magnetic field is proportional to the current.

Therefore, all features of claim 1 are considered disclosed in D1 and hence, the subject matter of claim 1 is considered not new (Article 33(2) PCT).

3. DEPENDENT CLAIMS 2-11

Dependent claims 2-11 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

3.1 The features as defined in dependent claims 2-10 relate to straightforward features in the field of electrical signal processing circuitry.

Document D2, for example, discloses such a digital signal generator as defined in claims 2-4 (page 7, col. 12, lines 12-27, and paragraph 0105).

The features of dependent claims 5-10 are also common in the field of electric signal processing and generators.

3.2 Claim 11

Flexible coils and solenoids for treating the human body with a magnetic field are well known in the art, see for example document D3, column 3, line 58 to column 4, line 48.

Re Item VIII.

The control probe(32) does not appear to be a part of the invention. Therefore, any reference to it in order to define the invention, leads to a lack of clarity (see PCT Guidelines of 25-03-2004, section 5.37).

C L A I M S

1. An electromagnetic field stimulator device for Anatomic Biophysical Chondroprotection, in which means of current generation (7, 18 and 20) are suitable for powering at least one solenoid (24) to generate an electromagnetic field directed on a part of the human body (26) including cartilaginous tissue (27), characterized in that the said means of current generation (7, 18 and 20) supplies said solenoid (24) with current $i(t)$ having a waveform that includes the repetition of a linear ramp with a certain slope; said current $i(t)$ causing the generation of an electromagnetic field that induces on a control probe (32) irradiated by said electromagnetic field, a voltage (V_{in}) of markedly constant amplitude during the ramp-like linear growth period of said current $i(t)$.

~~2.- A device according to claim 1, in which said means of current generation includes at least one table (7) in which at least one function $f(t)$ is stored that provides for each value of a scanning signal in input (sc), an output value that expresses a target current intensity (I_{out}), the said function $f(t)$ being a linear one and representing a ramp with a certain slope that supplies, for increasing values of said scanning signal in input (sc), linearly increasing values of said target current intensity (I_{out}).~~

3.- A device according to claim 2, in which said table (7) contains a number of functions $f(t)$ of different, selectable types.

4.- A device according to claim 2, in which timer devices (3 and 4) are provided that are suitable for generating said scanning signal in input (sc).

5.- A device according to claim 2, in which attenuator devices